

**REMARKS**

**I. STATUS OF CLAIMS**

Claims 1 and 4-60 are pending in this case based on the amendments to the claims provided herein and claims 31-59 were withdrawn from consideration pursuant to a restriction requirement.

Claim 1 was amended to incorporate an element recited in claim 10 as originally filed, i.e., that R<sub>1</sub> is chosen from linear and branched, saturated and unsaturated C<sub>8-40</sub> hydrocarbon-based radicals. Further to this amendment to independent claim 1, dependent claims 4, 5, 10, 12, 13, 16, 17, 23, and 24 were also amended in order to render the language of these dependent claims consistent with the language of claim 1. These amendments to the claims are fully supported in the specification and original claims.

In addition, new claim 60 was added and support for this new claim can be found in original claim 10. Accordingly, no new matter is added by these amendments.

**II. REJECTION UNDER 35 U.S.C. § 112**

The Office maintains the rejection of claims 1 and 4-30 under 35 U.S.C. § 112, second paragraph “as being *indefinite* for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.” Office Action at page 2 (emphasis added). In particular, the Office contends that it is unclear what dermatological disorders are associated with “seborrhea” and/or “Propionibacterium acnes and Propionibacterium granulsum” and as such, the metes and bounds of the

claimed invention is indefinite. *Id.* Applicants continue to respectfully disagree for the reasons of record and for the following additional reasons.

According to M.P.E.P. § 2173.02, “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” M.P.E.P. § 2173.02 (8th ed. Rev. 3 2005). Based on this, the Office’s rationale for the rejection of the pending claims is clearly inadequate.

For example, it appears the Office’s rationale is based solely on what is expressly taught in the specification. That is, the Office finds that the claims are indefinite because the specification discloses “acne and hyperseborrhoea” as the dermatological disorders associated with “seborrhea” and/or “*Propinibacterium acnes* and *Propionibacterium granulosum*” but does not provide for others. Office Action at page 3, II. 12-15. The claims, however, must be read in light of not only the specification, but also the teachings of the prior art and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art. Without considering the claim language in view of these other factors, the Office cannot sustain an indefiniteness rejection.

For example, prior art such as U.S. Patent No. 6,040,347 at Col. 1, II. 10-27 describes, e.g., dermatological disorders associated with seborrhea and dermatological disorders associated with microorganisms chosen from *Propionibacterium acnes* and *Propionibacterium granulosum*. In contrast to the Office’s assertion, these references

identify teachings in the prior art as well as knowledge of a skilled artisan. Thus, the present language of the claims sets out and circumscribes the particular subject matter with a reasonable degree of clarity and particularity. See M.P.E.P. § 2173.02. Applicant thus respectfully requests the withdrawal of the rejection.

### **III. REJECTION UNDER 35 U.S.C. § 102(e)**

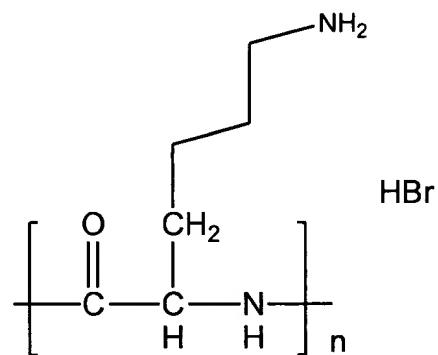
The Office also maintains the rejection of claims 1, 4-10, 12-15, 25-27, and 30 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,395,284 to Thunemann as evidenced by Aldrich. Office Action at page 4. In response to Applicants' arguments, the Office asserts that the present specification provides vitamins including retinol, *i.e.*, vitamin A, as something other than anti-seborrhoeic agents and thus, are useful in the claimed composition. *Id.* The Office then concludes that the cited reference containing vitamin A and a polyamino acid meets the claim limitations. *Id.* Applicants continue to respectfully disagree for the reasons of record. Nevertheless, in an attempt to expedite prosecution of the present application, Applicants have amended claim 1 in a manner that for the reasons set forth below further distinguishes the presently claimed invention from the prior art relied upon by the Examiner.

Thunemann teaches a composition of mesomorphic complexes of vitamin A acid and cationic polyelectrolytes. Thunemann at Abstract. Of the cationic polyelectrolytes disclosed, Thunemann specifically states that those that are "particularly preferably used are poly-L-amino acids in particular poly-L-arginine, poly-L-histidine, poly-L-lysine or a mixture thereof." *Id.* at Col. 3, ll. 3-5. The Office further cites Aldrich for the teaching that poly-L-lysine "having [an] average molecular weight in the range of

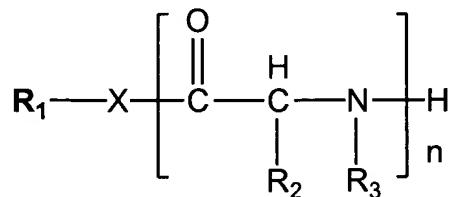
1K-70K [that] is commercially available." Office Action dated November 18, 2003, at page 5. But, the teaching of poly-L-amino acids, e.g., poly-L-lysine in Aldrich, is different from the presently amended claims.

As provided below, Thunemann's teaching of poly-L-amino acids, e.g., poly-L-lysine, does not correspond with polyamino acid derivatives of formula (I) and salts thereof that are recited in the amended claims. Below poly-L-lysine listed in Aldrich is compared to the formula currently recited in claim 1.

ALDRICH: poly-L-lysine hydrobromide molecular weight 30,000-70,000



Present invention: polyamino acid derivatives of formula (I) and salts thereof



where

X is chosen from O, S, NH and NR" wherein R" is chosen from saturated and unsaturated, linear and branched C<sub>1-6</sub> hydrocarbon-based radicals;

**R<sub>1</sub> is chosen from: linear and branched, saturated and unsaturated C<sub>8-40</sub>**

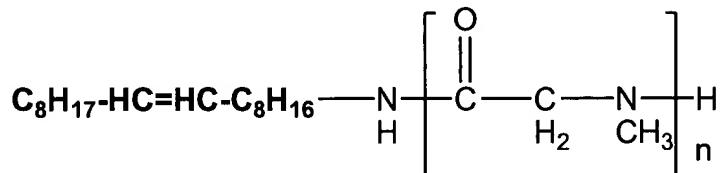
**hydrocarbon-based radicals,**

R<sub>2</sub> is chosen from hydrogen; saturated and unsaturated, linear and branched C<sub>1-8</sub> hydrocarbon-based radicals; and radicals chosen from -CH<sub>2</sub>C<sub>6</sub>H<sub>5</sub>, -CH<sub>2</sub>C<sub>6</sub>H<sub>4</sub>OH, -CH<sub>2</sub>OH, -CHOHCH<sub>3</sub>, -(CH<sub>2</sub>)<sub>t</sub>-NH<sub>2</sub>, wherein t is a number chosen from 3, 4 and 5;

R<sub>3</sub> is chosen from hydrogen and saturated and unsaturated, linear and branched C<sub>1-6</sub> hydrocarbon-based radicals; and

n is a number greater than 1 chosen such that the number average molecular weight of the polyamino acid derivative ranges from 150 to 200 000.

Examples of the polyamino acid derivatives of formula (I) as currently recited in claim 1 can be found, for example, in Example 1, described at page 13 of the present specification, which has the following formula:



where n = 9.8

As illustrated above, Aldrich or for that matter Thenemann does not teach or suggest polyamino derivatives as recited in the amended claims, e.g., with the particular R1 values. As provided under Section 102, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); see also, M.P.E.P. § 2131. In this case,

claim 1 (from which all the other rejected claims depend) recites particular R1 values outside the scope of Thunemann and thus, fails to teach each and every element as set-forth in the claims as required under Section 102. As such, Applicants respectfully request the withdrawal of the rejection.

#### IV. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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